



 $\{i$ 

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	-
	09/189,043	11/09/1998	SCOTT M. ROCKLAGE	238/117	5059	
	21834 7:	590 05/06/2002				
	BECK AND TYSVER 2900 THOMAS AVENUE SOUTH SUITE 100		EXAMIN		NER	
				HARTLEY, MICHAEL G		
	MINNEAPOLI	IS, MN 55419		ART UNIT	PAPER NUMBER	-
				1616	, /	_
				DATE MAILED: 05/06/2002	16	

Please find below and/or attached an Office communication concerning this application or proceeding.

1							
	Applicati n N .	Applicant(s)					
_	09/189,043	ROCKLAGE ET AL.					
Office Action Summary	Examin r	Art Unit					
	Michael G. Hartley	1616					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1)⊠ Responsive to communication(s) filed on <u>12 April 2002</u> .							
_	is action is non-final.						
3) Since this application is in condition for allowa							
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>							
	4) Claim(s) 1-4,8,21-24 and 28-30 is/are pending in the application.						
4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1-4,8,21,24 and 28-30</u> is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or	r election requirement.						
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the							
11) The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Example 1.12	aminer.						
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
Certified copies of the priority documents							
2. Certified copies of the priority documents have been received in Application No							
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received.  15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)					

U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)



Application/Control Number: 09/189,043

Art Unit: 1616

## Response to Amendment

The amendment filed 4/12/2002 has been entered. Claims 1, 2 and 21 have been amended. New claims 28-30 have been added.

#### Response to Arguments

Any previous rejections which have not been obviated herein have been withdrawn.

Applicant's arguments with respect to claims 1-4, 8, 21 and 28-30 have been considered but are most in view of the following new ground(s) of rejection.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 8 and 21 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Belliveau (SMRM 8, 8/1988) or Cacheris (SMRM 8, 8/1988) in view of Villringer.

Belliveau discloses methods of MRI comprising administering Dy-DPTA to a subject and measuring the perfusion of various brain areas, see column 2. High-speed imaging is used to ascertain changes between MRI signal intensity in gray and white matter of the brain. These changes would be within the scope of "variations" as claimed. Cacheris teach methods of intravascular contrast-enhanced susceptibility MRI to the brain to measure changes in signal intensity over time of brain perfusion. Cacheris discloses the use of Cy-DTPA-BMA, which is the same contrast as claimed. These changes would be within the scope of "variations' as instantly claimed.

Belliveau and Cacheris fail to specifically disclose that the perfusion rates are directly related to blood flow.

Villringer discloses the use of contrast agents to measure perfusion changes and teaches that perfusion is directly related to blood flow, see abstract.



Art Unit: 1616

It would have been obvious to one of ordinary skill in the art to measure blood flow in the perfusion imaging methods disclosed by Belliveau and/or Cacheris because it is known in the art that perfusion rates are directly related to blood flow and provide the advantage of yielding physiological data on blood flow for clinical use, as shown by Villringer.

Applicant's arguments filed 4/12/2002 have been fully considered but they are not persuasive.

The affidavit filed on 4/12/2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the rejection set forth above because the reference to which this affidavit is directed has been removed from the rejection based on applicant's amendment. The Rosen reference, which the affidavit is provided to swear behind, is no longer needed to in the rejection of the pending claims. The Rosen reference was relied upon for teaching that methods of MRI are used to produce <u>quantitative</u> values related to blood flow. However, the limitations related to obtain quantitative results of the blood flow have been deleted from the pending claims. Therefore, since the teaching of obtaining quantitative data is no longer present in the claims, the teaching thereof, as provided by the Rosen reference is no longer required in the rejection. Thus, the affidavit fails to overcome the new grounds of rejection as set forth above (and necessitated by applicant's amendment), which does not rely on the Rosen reference.

### **Double Patenting**

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain <u>a</u> patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 24 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 5,833,947, for the reasons set forth in the office action mailed 12/03/2001.

Applicant has not traversed this rejection with any substantive arguments and has indicated that a terminal disclaimer will be filed when the claims are otherwise allowable.



Application/Control Number: 09/189,043

Art Unit: 1616

NOTE: This is not found persuasive for the above rejection of claim 24, because this is a statutory double patenting rejection. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101. It is suggested that claim 24 is canceled to obviate this rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 8, 21 and 28-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,190,744, for the reasons set forth in the office action mailed 12/03/2001.

Applicant has not traversed this rejection with any substantive arguments and has indicated that a terminal disclaimer will be filed when the claims are otherwise allowable. Therefore, this rejection is maintained until said terminal disclaimer is filed.

Page 5



Application/Control Number: 09/189,043

Art Unit: 1616

### Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

#### Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Primary Examiner Art Unit 1616

МН

May 2, 2002